

## **REMARKS**

In response to the above-identified Office Action, Applicants traverse the Examiner's rejection to the claims and seek reconsideration thereof. Claims 11-20 are now pending in the present application. In this response, claims 11, 13 and 14 are amended, no claims are added and no claims are cancelled.

The instant application is directed to a microfluidic device comprising a sensing substrate bound to a channel substrate, the sensing substrate including a sensing electrode, an electrode interconnect and an electrode pad, the channel substrate including a first fluid inlet port at a side of the channel substrate, a first fluid addition chamber around the first fluid inlet port, a sample reaction barrier connecting a sensing chamber with the first fluid addition chamber, and a second fluid inlet port at the other side of the channel substrate, a second fluid addition chamber around the second fluid inlet port, a channel connecting the second fluid addition chamber and the sensing chamber, and a used reagent reservoir connected to the sensing chamber; a first fluid comprising a sample for loading into the sensing chamber via the first fluid inlet port and a second fluid comprising a buffer solution for loading into the sensing chamber via the second fluid inlet port; an external pump for forcing fluid flow from the second fluid inlet port to the sensing chamber; and wherein the channel substrate is dimensioned such that a sample loaded via the first fluid inlet port flows into the sensing chamber through the first fluid addition chamber solely by capillary force, the sensing chamber having outlets which are larger than an inlet of the sensing chamber such that the capillary force diminishes at the sensing chamber outlets, and a buffer solution loaded via the second fluid inlet port flows by the action of the external pump through the channel and the sensing chamber, for washing reacted products, and is reserved in the used reagent reservoir.

### **I. Examiner Interview**

An Examiner Interview was conducted on January 4, 2007 between Examiner Natalia Levkovich and Applicants' attorney Stacie J. Sundquist. During the interview claim 11 and the rejections to claim 11 under 35 USC §112 were discussed. Various amendments were discussed to overcome the rejection of claim 11 under 35 USC §112. Applicants believe the attached

amendments to claim 11 incorporate the language proposed by the Examiner during the Examiner Interview.

## **II. Claim Amendment**

In the instant response claim 11 is amended to positively claim the elements of a sample, a buffer solution and an external pump. Claim 11 is further amended to recite the structural relationship between the sensing chamber, first fluid addition chamber and sample reaction barrier. In addition, claim 11 is amended to clarify that “the channel substrate is dimensioned such that a sample loaded via the first fluid inlet port flows into the sensing chamber through the first fluid addition chamber solely by capillary force, the sensing chamber having outlets which are larger than inlets of the sensing chamber such that the capillary force diminishes at the sensing chamber outlets.” Support for the amendments may be found, for example, on page 14, lines 15-23 and on page 15 of the application. Claims 13 and 14 are amended to correct the recitation of “and/or” to recite “or.” Since the amendments are supported by the specification and do not add new matter, Applicants respectfully request consideration and entry of the amendments to claims 11, 13 and 14.

## **III. Claim Rejections – 35 U.S.C. §112, second paragraph**

In the outstanding Office Action, the Examiner rejects claims 11-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the Examiner alleges the recitation of “injecting” the sample via the first fluid inlet port implies the sample is driven by an external force, not a capillary force as recited in the claim. See Action, page 3. The Examiner further concludes the buffer driven from the second fluid inlet port by an external pump is “inevitably subject to the capillary force” and that this portion of the claim is merely a narrative lacking structural features. See Action, page 3. The Examiner further suggests even if a structure is found within this portion of the claim, any structure providing for the capillary flow from the first fluid inlet port is the same as that which allows for the forced flow of the buffer solution from the second fluid inlet port using an external pump. See Action, page 3. The Examiner, however, fails to point to any portion of the application supporting such a reading of

the claim language. Instead, these conclusions appear to be based on the Examiner's conjecture alone. Conjecture, however, is not a sufficient basis for finding claim language indefinite.

In addition, the Examiner states the "external pump" is not positively claimed. Applicants do not understand on what basis the Examiner finds the "external pump" which is expressly recited in the claim is not positively claimed.

Although for at least the foregoing reasons, Applicants disagree with the Examiner's findings, in an effort to expedite prosecution of this case, Applicants have amended claim 11 to more clearly indicate the external pump is an element of the claim, to clarify the structural features of the claim and delete the recitation of "appreciably large" which the Examiner alleges is indefinite.

Applicants believe in view of the foregoing arguments and the amendments to claim 11, claim 11 and its dependent claims are in compliance with 35 U.S.C. 112, second paragraph, Applicants respectfully request reconsideration and withdrawal of the rejection to claims 11-20 on this basis.

#### **IV. Claim Rejections – 35 U.S.C. §103**

In the outstanding Action the Examiner rejects claims 11-20 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,632,400 issued to Brennen et al. ("Brennen") in view of U.S. Patent No. 6,827,906 issued to Bjornson et al. ("Bjornson"). Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, the Examiner must show that the cited reference teaches or suggests each of the elements of a claim. Hindsight reconstruction may not be used to modify the reference to meet the claimed invention. MPEP § 2145. Furthermore, the fact that the claimed invention is within the capabilities of one of ordinary skill in the art, without some showing of an objective reason for modifying the reference to arrive at the claimed invention, is not sufficient to establish a *prima facie* case of obviousness. *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000).

In regard to claim 11, Applicants respectfully submit Brennen in view of Bjornson fails to teach or suggest at least the elements of a “channel substrate including a first fluid inlet port at a side of the channel substrate, a first fluid addition chamber around the first fluid inlet port, a sample reaction barrier connecting a sensing chamber with the first fluid addition chamber, and a second fluid inlet port at the other side of the channel substrate, a second fluid addition chamber around the second fluid inlet port, a channel connecting the second fluid addition chamber and the sensing chamber, and a used reagent reservoir connected to the sensing chamber,” “a first fluid for loading into the sensing chamber via the first fluid inlet port and a second fluid comprising a buffer solution for loading into the sensing chamber via the second fluid inlet port” and “wherein the channel substrate is dimensioned such that a sample loaded via the first fluid inlet port flows into the sensing chamber through the first fluid addition chamber solely by capillary force, the sensing chamber having outlets which are larger than an inlet of the sensing chamber such that the capillary force diminishes at the sensing chamber outlet, and a buffer solution loaded via the second fluid inlet port flows by the action of the external pump through the channel and the sensing chamber, for washing reacted products, and is reserved in the used reagent reservoir” as recited in claim 11.

Brennen generally teaches integrated microfluidic and electronic components. As admitted by the Examiner, Brennen fails to specifically teach the particular microfluidic layout as recited in claim 11. See Action, page 4. The Examiner has further not pointed to a portion of Brennen teaching the recited components of the channel substrate having the recited structural relationships such as the “first fluid inlet port,” “first fluid addition chamber around the first fluid inlet port,” “a sample reaction barrier connecting a sensing chamber with the first fluid addition chamber,” “a second fluid addition chamber around the second fluid inlet port,” “a used reagent reservoir,” “the sensing chamber having outlets which are larger an inlet of the sensing chamber” and “a reaction barrier” as well as “an external pump” or the use of solely capillary force for control of fluid flow through the system. Instead, the Examiner generally alleges Brennen’s teaching of channels, compartments and flow control elements teaches these elements. See Action, page 4. Applicants respectfully submit, such a general disclosure does not teach or suggest each of the above recited elements.

Bjornson further fails to cure the deficiencies of Brennen with respect to these elements. The Examiner alleges Figure 9 of Bjornson discloses a structure having two inlets (102, 116) on two different sides of the structure and connected to a sensing chamber (135), and a reaction chamber (125). See Action, page 5. The Examiner further alleges “[t]he inlets appear to be surrounded by chambers which can serve as ‘addition chambers’” (emphasis added). See Action, page 5. The Examiner further alleges “the unmarked sections of the main channel...can be referred to as ‘reaction barrier’ and ‘time delay’.” See Action, page 5.

Applicants respectfully submit, a *prima facie* case of obviousness may not be based on what a reference “appears” to teach. Nowhere within Bjornson is it suggested fluid addition chambers surround elements 102 and 116 or that the circles illustrating elements 102 and 116 represent chambers surrounding these elements. Thus, the Examiner has not shown that Bjornson teaches or suggests at least the elements of “a first fluid addition chamber around a first fluid inlet port” and “a second fluid addition chamber around a second fluid inlet port.”

The Examiner further fails to identify any portion of Bjornson identifying an unmarked section of the main channel as “a sample reaction barrier connecting a sensing chamber with the first fluid addition chamber” as further recited in claim 11. Moreover, since the portion of Figure 9 relied upon by the Examiner is unmarked, it is unclear to Applicants which portion of the reference the Examiner is relying upon to teach this element. For at least the foregoing reasons, an unmarked region in Figure 9 of Bjornson which is further not described within the reference may not be relied upon to teach “a sample reaction barrier.” Applicants respectfully request the Examiner particularly point out the portion of Bjornson being relied upon to teach this element if the Examiner chooses to maintain the rejection of claim 11 on this basis.

Lastly, the Examiner has not pointed to a portion of Bjornson teaching the elements of “wherein the channel substrate is dimensioned such that a sample loaded via the first fluid inlet port flows into the sensing chamber through the first fluid addition chamber solely by capillary force and stops flowing at the sensing chamber having outlets which are larger than an inlet of the sensing chamber such that the capillary force diminishes at the sensing chamber outlet, and a buffer solution loaded via the second fluid inlet port flows by the action of the external pump

through the channel and the sensing chamber, for washing reacted products, and is reserved in the used reagent reservoir.”

For at least the reasons that the Examiner has failed to establish that Brennen in view of Bjornson teaches each of the above recited elements of claim 11, a *prima facie* case of obviousness may not be established. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. §103 over Brennen in view of Bjornson.

In regard to claim 12, claim 12 depends from claim 11 and incorporates the limitations thereof. Thus, for at least the reasons that claim 11 is not *prima facie* obvious over Brennen in view of Bjornson, claim 12 is not obvious over the references. Claim 12 is further not obvious over the references for at least the reason that the Examiner has failed to identify a portion of the references teaching the additional element of “a reaction chamber and a time delay between the reaction barrier and the sensing chamber” as further recited in claim 12. The Examiner recognizes the failure of Brennen to teach or suggest these elements and instead alleges the unmarked sections of the main channel in Bjornson can be referred to as a reaction barrier and time delay. Applicants have reviewed Bjornson and are unable to discern a portion of Bjornson suggesting a time delay between the reaction barrier and the sensing chamber, much less that an unmarked portion of Figure 9 illustrates such a time delay. If the Examiner chooses to maintain the rejection of claim 12 on this basis, Applicants respectfully request the Examiner specify the portion of Bjornson relied upon to teach this element. Thus, for at least these additional reasons, claim 12 is not *prima facie* case of obviousness over Brennen in view of Bjornson. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 12 under 35 U.S.C. §103 over Brennen in view of Bjornson.

In regard to claims 13-14, these claims depend from claim 11 and incorporate the limitations thereof. Thus, for at least the reasons that claim 11 is not *prima facie* obvious over Brennen in view of Bjornson, claims 13-14 are not obvious over the references. Claims 13-14 are further not obvious over the references for at least the reason that there is no motivation to modify Brennen to teach the additional element of “wherein the sensing substrate further comprises recesses to correspond to the multiple fluid inlet ports, the chamber or the channel” as

recited in claims 13-14. The Examiner alleges Brennen teaches direct contacts to the fluid and therefore it would have been obvious to modify Brennen to include recesses located over corresponding fluidic elements to better accommodate the electrical elements. See Action, page 5. Brennen, however, teaches these contacts are formed by conductive traces such as those found on a printed circuit board. See Brennen, col. 3, lines 2-4 and 22-23. One of ordinary skill in the art, however, would understand conductive traces of a printed circuit board to be formed on a substrate, not embedded within recesses formed in the substrate. Even if it were possible to find Brennen suggests the use of recesses, and Applicants do not believe it is, there is no indication from Brennen that the direct contacts are positioned over fluidic elements such as those recited in claims 13-14 as alleged by the Examiner. Moreover, as previously discussed, the Examiner has not shown that Brennen teaches or suggests each of the claimed fluid inlet ports, chamber or channel thus one of ordinary skill in the art would not understand to form recesses to each of these components to accommodate the conductive traces of Brennen as would be required by claims 13-14. Thus, it appears it is only upon viewing Applicants' disclosure that the motivation to modify Brennen to include "recesses to correspond to the multiple fluid inlet ports, the chamber, or the channel" would be recognized. As the Examiner is no doubt aware, such hindsight reconstruction is inappropriate as a matter of law. Thus, for at least these additional reasons, claims 13-14 are not *prima facie* case of obviousness over Brennen in view of Bjornson. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 13-14 under 35 U.S.C. §103 over Brennen in view of Bjornson.

In regard to claims 15-20, these claims depend from claim 11 and incorporate the limitations thereof. Thus, for at least the reasons that claim 11 is not *prima facie* obvious over Brennen in view of Bjornson, claims 15-20 are further not obvious over the references. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 15-20 under 35 U.S.C. §103 over Brennen in view of Bjornson.

### **CONCLUSION**

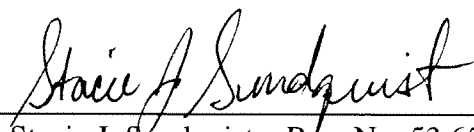
In view of the foregoing, it is believed that all claims now pending, namely claims 11-20, are now in condition for allowance and such action is earnestly solicited at the earliest possible date. If there are any additional fees due in connection with the filing of this response, please charge those fees to our Deposit Account No. 02-2666. Questions regarding this matter should be directed to the undersigned at (310) 207-3800.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR, & ZAFMAN LLP

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By: \_\_\_\_\_

  
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### **CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being submitted electronically via EFS Web to the United States Patent and Trademark Office on January 8, 2007.

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